UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,174	02/26/2004	Michel Franz	09997.0087US01	9902

23552 7590 05/12/2006

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,174	FRANZ, MICHEL	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment, remarks, and arguments, filed 4/13/06 and supplemental amendment and remarks filed 4/14/06 have been received. Claim 15 is cancelled by amendment, and claims 16 and 17 are added. Claims 1 – 14, 16 and 17 are pending in this action.

Priority

Receipt of Applicants' European Priority documents, filed 3/21/2006, is acknowledged.

Claim Rejections - 35 USC § 112

In light of amendment, and the cancellation of claim 15, the rejection of claims 1, 3, 5 and 15 under the first paragraph of 35 U.S.C. 112 is **withdrawn**.

In light of amendment and the cancellation of claim 15, the rejection of claims 1, 5, 6, and 15 under the second paragraph of 35 U.S.C. 112 is **withdrawn.**

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 – 9 and 11 – 14 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by US 5,601,843 to Gimet et al. for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant argues that Gimet does not disclose tablets with "retardant material", as required by instant claims, and therefore, that the tablets of Gimet will not display extended release of the NSAID.

It is noted, however, that instant claim 4 lists retardant materials, and included in this list are "lipidic materials", "cellulose-based polymers", and "a mixture thereof". The "first region" of Gimet's dosage form (the core in Gimet's examples) clearly contains diclofeac sodium (a NSAID), microcrystalline cellulose (a cellulose-based polymer) and magnesium stearate (a lipidic material, based on the lipid stearic acid). These materials clearly meet the requirements of retardant materials as outlined by Applicant in instant claim 4. As such, the dosage forms of Gimet, being made from the same components as those of instant claims wherein those components are arranged in the same manner with respect to each other, must have the same properties as the dosage form of instant claims.

Claims 1 – 9 **remain** rejected under 35 U.S.C. 102(b) as being anticipated by US 5,213,807 to Cheburkar et al. for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant argues that Cherburkar does not disclose tablets with an NSAID mixed with a "retardant material", as required by instant claims.

It is noted, however, that instant claim 4 lists retardant materials, and included in this list are "lipidic materials", "cellulose-based polymers", and "a mixture thereof". Cherburkar discloses a "first region" (the core in Examples) that contains the NSAID ibuprofen mixed with the lipidic material stearic acid. As such, the compositional requirements regarding a "retardant material", as defined by instant claims, are met by this reference.

The rejection of claims 1 – 6 and 8 – 14 under 35 U.S.C. 102(b) as anticipated by US 6,183,779 to Ouali et al. is **withdrawn**. Since applicant has perfected priority, Ouali no longer qualifies as prior art under 35 U.S.C. 102(b).

Claims 1 – 6 and 8 – 14 are rejected under 35 U.S.C. 102(a) as being anticipated by US 6,183,779 to Ouali et al. for reasons discussed in the previous office action, and those below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant argues that Ouali does not disclose tablets with an NSAID mixed with a "retardant material", as required by instant claims.

It is noted, however, that instant claim 4 lists retardant materials, and included in this list are "lipidic materials", "cellulose-based polymers", and "a mixture thereof". The first region of Ouali comprises granules, which comprise the NSAID diclofenac and the cellulose-based material microcrystalline cellulose.

Claims 1 – 9 and 11 **remain** rejected under 35 U.S.C. 102(e) as being anticipated by US 6,656,503 B1 to Sherman for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant argues that Sherman does not disclose tablets with an NSAID mixed with a "retardant material", as required by instant claims.

It is noted, however, that instant claim 4 lists retardant materials, and included in this list are "lipidic materials", "cellulose-based polymers", and "a mixture thereof". Sherman discloses an NSAID mixed with a lipidic material, magnesium stearate, and a cellulose-based polymer, microcrystalline cellulose. Thus, the compositional requirements of instant claims are met.

Claims 1 – 6 and 9 – 11 **remain** rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0054908 by Woolfe et al. for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant argues that Woolfe does not disclose tablets with an NSAID mixed with a "retardant material", as required by instant claims.

It is noted, however, that instant claim 4 lists retardant materials, and included in this list are "lipidic materials", "cellulose-based polymers", and "a mixture thereof".

Woolfe discloses a NSAID, diclofenac, as beads mixed with microcrystalline cellulose, a cellulose based polymer, and stearic acid, a lipidic material (example 2). As such, the compositional requirements of instant claims are met.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12 – 14 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0054908 by Woolfe et al. for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant argues that Woolfe does not disclose tablets with an NSAID mixed with a "retardant material", as required by instant claims.

It is noted, however, that instant claim 4 lists retardant materials, and included in this list are "lipidic materials", "cellulose-based polymers", and "a mixture thereof". Woolfe discloses a NSAID, diclofenac, as beads mixed with microcrystalline cellulose, a cellulose based polymer, and stearic acid, a lipidic material (example 2). As such, the compositional requirements of instant claims are met.

Claims 12 – 14 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,213,807 to Cheburkar et al. or US 6,656,503 B1 to Sherman in either case in view of US 6,183,779 to Ouali et al. for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicant avers that Cheburkar and Sherman have deficiencies that are not met by Ouali. These alleged deficiencies have been discussed, *supra*.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0054908 by Woolfe et al. in view of US 2003/0138486 by Ouadji.

Woolfe teaches a pharmaceutical dosage form including a mixture of delayed release NSAIDbeads and a mixture containing a prostaglandin (abstract). The composition is, in one embodiment, a capsule, such as a hard gelatin capsule (paragraph 0026). In this embodiment the capsule is filled with delayed release ketoprefen beads, misoprestol diluted with HPMC, and other excipients (example 1). The delayed release beads comprise the NDAID mixed with microcrystalline cellulose and stearic acid (example 2).

Woolfe does not teach hydroxypropyl cellulose capsules.

Ouadji teaches that HPMC capsules and gelatin capsules are equivalents in the art of capsular dosage forms (paragraph 0027).

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use a HPMC capsule instead of a gelatin capsule. It is generally obvious to substitute art-recognized equivalents for one another, when the equivalents are used for their art-intended and recognized uses. In this case, HPMC capsule shells and gelatin capsule shells are both recognized as equivalents for the purpose of encapsulating powder or granular medicaments.

Conclusion

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric E. Silverman, PhD
Art Unit 1615

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600